

REMARKS

The Office Action rejected claims 18, 19, 21-31, 33-45 and 48-65. Claims 1-17, 20, 32, 46 and 47 were previously canceled. By this Amendment, to expedite prosecution of this application, claims 18, 43, and 50 are amended.

Interview Summary

The applicant thanks Examiner Bertram for his participation in a telephone interview with the undersigned. The participants discussed amending the claims to overcome the rejections based on the references discussed below. The participants discussed the amendments made to the claims herein and agreed that these amendments overcome the pending rejections.

Priority Claim

As requested in the Office action, an English translation of the certified copy of the priority document (German Patent Application 103 16 177.5) is enclosed. This translation establishes that the present invention is entitled to rely on the filing date (April 9, 2003) of the priority application. Accordingly, U.S. Patent 7,418,298 is not prior art under section 102(e).

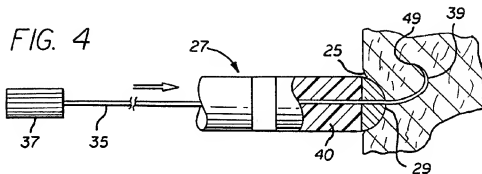
Obviousness-Type Double Patenting Rejections

The Office action rejects various claims of the present application on the grounds of nonstatutory obviousness-type double patenting in view of commonly owned U.S. patent application 10/971,577 (now U.S. Patent 7,499,757), U.S. Patent 7,418,298, and U.S. patent application 10/972,298 (now U.S. Patent 7,499,759). While applicant disagrees with this rejection, it is amendable to submitting a terminal disclaimer to overcome these rejections, upon reaching agreement that the claims stand in allowable form.

Section 102 Rejections

The Office action rejected claims 18, 22, 43, 44, and 50 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 5,492,119 ("*Abrams*"). *Abrams* is directed to an electrophysiology catheter intended for use in cardiac tissue ablation. (*Abrams*, 1:54-66.) As shown in Figure 4 (reproduced below), and as explained in the specification, *Abrams* discloses a catheter tube 27 having an RF electrode 29 at the distal end. *Abrams* recognizes that "benefits inure in repeatedly

positioning and anchoring the catheter distal tip relative to several endocardial sites within a patient's intracardial volume.” (*Abrams*, 2:6-9.) In other words, it is directed to a design that is readily repositionable to allow anchoring to various sites within the heart. To this end, *Abrams* discloses a configuration that uses a “hook shaped foot 39,” which is made of a material allowing repeated deformation between a J-shape and a straight shape. (*Abrams*, 5:13-25.)



In use, the catheter tube 27 is introduced and manipulated to “position the distal tip in axial alignment with the specific tissue 25 to be mapped.” (*Abrams*, 5:27-35.) Next, the “control wire 35” is “advanced telescopically relative to the catheter tube to thus project the sharp point 49 of the foot 39 from the distal port 33 to thus penetrate the tissue 25 forming the wall of the ventricle.” (*Abrams*, 5:37-46.) After the ablation procedure is completed, the foot 39 is removed. Specifically, the “distal extremity of the catheter tube 27 has a certain degree of semi-rigidity to the point where it will overcome the inherent bias of the pseudo-elastic foot section 39 upon retraction thereof into the distal segment 40 to thus effect straightening to form a linear configuration as it withdrawn into the lumen 31.” (*Abrams*, 6:20-25.) This configuration allows for “retraction out the path cut in the tissue to avoid the trauma which would be otherwise associated with withdrawal of the hook shaped foot,” such that the catheter may be readily removed from the patient. (*Abrams*, 6:28-37.)

Independent claims 18, 43, and 50, as amended, each require an anchor configured to “anchor against an outside surface of the heart.” *Abrams* does not disclose any structure meeting this claim limitation. To the contrary, *Abrams* discloses only embedding a hook into the myocardium, to allow the hook to be readily removed. Further, each of claims 18, 43, and 50 require that the electrode and tension element are configured such that “the electrode can be

threaded over the proximal end of the tension element.” As shown in Figure 4 (reproduced above), *Abrams* discloses a control wire 35 having a handle 37, which handle is substantially larger than the lumen 31 of the catheter 37. Accordingly, it would not be possible to thread the electrode over the proximal end of the tension element. Finally, each of claims 18, 43, and 50 are directed to a configuration having an anchor “structurally independent from” or “fastened to” the tension element. *Abrams*, as discussed above, does not disclose such a configuration. Thus, claims 18, 43, and 50, and the various claims depending therefrom, are patentable over *Abrams*.

The Office action rejected claims 18, 22, 33, 36, 43, 44 and 50 under 35 U.S.C. § 102(e) as anticipated by U.S. Publication 2003/0204231 (“*Hine*”). *Hine* is directed to a lead configuration adapted for positioning in the venous system and in particular the cardiac veins. (*Hine*, ¶ 7.) As shown in Figure 3A (reproduced below), *Hine* discloses a “lead 202” having a “stent 204,” which is positioned in a coronary vein.

Independent claims 18, 43, and 50, as amended, each require an anchor configured to “anchor against an outside surface of the heart.” The stent 204 disclosed in *Hine* is not capable of anchoring against an epicardial surface. To the contrary, *Hine* only discloses a stent capable of being positioned in portions of the coronary venous system. Furthermore, a skilled artisan, assumed to be endowed with “common sense,” would not modify the system of *Hine* to include this limitation, as any such modification would result in an embodiment unsuitable for its intended purpose (i.e., positioning in the coronary venous system). Moreover, *Hine* expressly distinguishes over surgically implanted leads by stating that “Among the many advantages of transvenous leads is that they permit an electrical contact with the heart without physically exposing the heart itself, i.e., major thoracic surgery is not required.” (*Hine*, ¶ 5.) Thus, claims 18, 43, and 50, and the various claims depending therefrom, are patentable over *Hine*.

Section 103 Rejections

The Office action rejected claims 38 and 48 under 35 U.S.C. § 103(a) as obvious over U.S. Publication 2003/0204231 (“*Hine*”). The Office action rejected claims 39, 40 and 49 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication 2003/0204231 (“*Hine*”) in view of U.S. Patent 3,244,174 (“*Wesby*”). The Office action rejected claims 39, 40 and 49 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 7,418,298 (“*Shiroff*”) in view of U.S. Patent 3,244,174 (“*Wesby*”). For the reasons set forth above, one of ordinary skill in the art

would have no reason to combine or modify any of the cited references to arrive at the invention claims in any of independent claims 18, 43, or 50. Thus, claims 18, 43, and 50, and the various claims depending therefrom, are patentable over the cited art.

Conclusion

For the reasons explained above, all pending claims are now in condition for allowance. Accordingly, the applicant respectfully requests that the Office issue a Notice of Allowance. Any amendments to the claims are made to expedite prosecution of this application, without acquiescing to the Office's rejections or characterizations of the claims or references in the Office Action. Even if not expressly discussed above, the applicant respectfully traverses each of the rejections, assertions, and characterizations regarding the disclosure and teachings of the cited references, including the prior art status and the propriety of proposed combinations of cited references. The applicant has made a good faith effort to respond to all rejections set forth in the Office Action and to place the pending claims in condition for immediate allowance. If the Examiner has any questions or comments, the Examiner is requested to contact the undersigned at 612-766-7436.

Respectfully submitted,

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